IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. TAMACIO WALLS, Defendant.	INDICTMENT 1:15 CR 217 CASE NO._____ Title 21, U.S.C., Sections 331(k) and 333(a)(2); Title 18, U.S.C., Section 2320(a) JUDGE GWIN

The Grand Jury charges:

GENERAL ALLEGATIONS

At all times material to this indictment:

1. The United States Food and Drug Administration (hereinafter "FDA") was the agency of the United States responsible for protecting the health and safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act, Title 21, United States Code, Section 301, *et. seq.* ("FDCA"). Among the purposes of the FDCA was to ensure that drugs sold for consumption or administration to humans were safe, effective, and bear labeling containing only true and accurate information. The FDA's responsibilities under the FDCA

included regulating the manufacture, labeling and distribution of all drugs shipped or received in interstate commerce.

2. Under the FDCA, drugs were defined as articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man (Title 21, U.S.C., § 321(g)(1)(B)); articles intended to affect the structure or function of the body of man (Title 21, U.S.C., § 321(g)(1)(C)); and articles intended for use as components of other drugs (Title 21, U.S.C., § 321(g)(1)(D)).

3. Under the FDCA, "prescription drugs" are those drugs which, because of their toxicity or other potentially harmful effects, or the method of their use, or collateral measures necessary for their use, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, or which were required to be administered under the professional supervision of a practitioner licensed to administer such drugs as a condition of FDA approving any such drugs to be placed on the market.

4. All controlled substances are "prescription drugs." Controlled substances can only be lawfully distributed to individuals with a valid prescription issued by a physician or other authorized health practitioner, except when dispensed directly to a patient by the practitioner (other than a pharmacist).

5. 21 C.F.R., § 1306.04, which governs the issuance of prescriptions for controlled substances, requires that every prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his/her professional practice. A prescription is not valid unless it meets this standard.

6. Under Title 21 U.S.C., § 353(b)(1), the act of dispensing prescription drugs without a valid prescription of a practitioner licensed by law to administer such drug is an act

which causes the drug so dispensed to become "misbranded." The subsequent introduction for delivery into interstate commerce of any drug that is "misbranded" is a violation of Title 21, U.S.C., §§ 331(a) and 353(b)(1).

7. "Viagra" was a drug within the meaning of Title 21, U.S.C., § 321(g)(1), (2), (3), and a prescription drug within the meaning of Title 21, U.S.C., § 353(b)(1)(A), in that, due to its toxicity and other potentiality for harmful effect, Viagra (sildenafil citrate) was not safe for use except under the supervision of a practitioner licensed by law to administer such drug. Viagra was the trade name for Pfizer, Inc.'s FDA approved erectile dysfunction drug containing the active ingredient sildenafil citrate. FDA had not approved any generic drugs containing sildenafil citrate.

8. "Cialis" was a drug within the meaning of 21 U.S.C., § 321(g)(1), (2), (3), and a prescription drug within the meaning of 21 U.S.C., § 353(b)(1)(A), in that, due to its toxicity and other potentiality for harmful effect, Cialis (tadalafil) was not safe for use except under the supervision of a practitioner licensed by law to administer such drug. Cialis was the trade name for Eli Lilly & Company's FDA approved erectile dysfunction drug containing the active ingredient tadalafil. FDA had not approved any generic drugs containing tadalafil.

9. "Levitra" was a drug within the meaning of 21 U.S.C., § 321(g)(1), (2), (3), and a prescription drug within the meaning of 21 U.S.C., § 353(b)(1)(A), in that, due to its toxicity and other potentiality for harmful effect, Levitra (vardenafil) was not safe for use except under the supervision of a practitioner licensed by law to administer such drug. Levitra was the trade name for Bayer, Inc.'s FDA approved erectile dysfunction drug containing the active ingredient vardenafil. FDA had not approved any generic drugs containing vardenafil.

10. The FDA-approved Package inserts (labeling) for Viagra, Cialis and Levitra each stated that these drugs were indicated for the treatment of erectile dysfunction. The labeling also stated that the evaluation of erectile dysfunction should include a determination of potential underlying causes and the identification of appropriate treatment following a complete medical assessment. The FDA-approved labeling for Viagra, Cialis and Levitra warned: (1) of a potential for cardiac risk in certain patients; (2) that prior to prescribing Viagra, Cialis or Levitra, physicians should carefully consider whether their patients with underlying cardiovascular disease could be affected adversely; and (3) that there was no controlled clinical data on the safety or efficacy of these drugs.

11. The FDCA makes it unlawful to commit any act with respect to a drug if the act was done while the drug was held for sale after shipment in interstate commerce and resulted in the drug being misbranded. Title 21, U.S.C., § 331(k). Under the FDCA, dispensing a prescription drug, such as Viagra (sildenafil citrate), Cialis (tadalafil) or Levitra (vardenafil) without the prescription of a physician is an act which results in the drug dispensed being misbranded while held for sale, under Title 21, U.S.C., § 353(b)(1).

12. Because Viagra, Cialis and Levitra were commonly known to be drugs that were related to sexual function, a market for Viagra (sildenafil citrate), Cialis (tadalafil) and Levitra (vardenafil) sprang up outside of the normal contours of doctor-patient relationships. In this market, consumers acquired Viagra (sildenafil citrate), Cialis (tadalafil) and Levitra (vardenafil) without receiving the protections from misuse that were attendant to acquiring the drugs through physicians, as contemplated in the FDA approved labeling. In doing so, consumers were falsely led to believe that taking Viagra (sildenafil citrate), Cialis (tadalafil) and Levitra (vardenafil) was safe and free from serious potential side effects.

13. The Defendant, TAMACIO WALLS, resided in Mansfield, Ohio, within the Northern District of Ohio, Eastern Division. From his residence within the City of Mansfield, Ohio, and elsewhere, Defendant offered for sale, and dispensed counterfeit versions of Viagra (active ingredient Sildenafil citrate), Cialis (active ingredient Tadalafil) and Levitra (active ingredient Vardenafil) to consumers without requiring consumers to provide any form of prescription before receiving said drugs. Defendant also did not inform consumers that said drugs were prescription drugs and that consumers should seek medical advice before consuming said drugs, nor did Defendant provide any warnings to consumers concerning potential dangers associated with taking said prescription drugs.

14. Although Defendant purchased, warehoused and dispensed these prescription drugs, he did not submit to regulation by FDA or regulatory bodies within the State of Ohio responsible for regulating the business of pharmacies. Defendant obtained these prescription drugs from unauthorized sources in China and India. When the drugs were shipped to the Defendant, the customs declarations forms accompanying the shipments typically misrepresented the content of the packages as non-pharmaceutical items such as "jackets and sportswear", "everyday items", and "boxes for mama" in an attempt to avoid detection and seizure by U.S. Customs officials.

COUNT 1

The Grand Jury further charges:

15. The allegations in paragraphs 1 through 14 are incorporated by reference and realleged as if rewritten herein.

16. Between on or about August 5, 2012, and on or about June 27, 2013, in the Northern District of Ohio, Eastern Division, and elsewhere, defendant, TAMACIO WALLS,

with the intent to defraud and mislead, did dispense without the prescription of a practitioner licensed by law, Title 21, U.S.C., Section 353(b), to administer Viagra (sildenafil citrate), Cialis (tadalafil) and Levitra (vardenafil), and the Defendant did so while the Viagra (sildenafil citrate), Cialis (tadalafil) and Levitra (vardenafil) was held for sale after shipment in interstate commerce and the act resulted in the drugs Viagra (sildenafil citrate), Cialis (tadalafil) and Levitra (vardenafil) being misbranded, all in violation of Title 21, United States Code, §§ 331(k) and 333(a)(2).

COUNT 2

The Grand Jury further charges:

17. The allegations in paragraphs 1 through 14 are incorporated by reference and realleged as if rewritten herein.

18. Between on or about August 5, 2012, and on or about June 27, 2103 , in the Northern District of Ohio, Eastern Division, and elsewhere, defendant, TAMACIO WALLS, did intentionally traffic in, and attempt to traffic in goods, specifically counterfeit Viagra pills (active ingredient sildenafil citrate), while knowingly using on and in connection with such goods, certain counterfeit trademarks, to wit: pill color, pill shape and other markings thereon which were identical to, and substantially indistinguishable from, marks that were in use and registered for those goods on the principle register of the United States Patent and Trademark Office, the use of said counterfeit marks being likely to cause confusion, mistake and to deceive, in violation of Title 18, United States Code, § 2320(a).

A TRUE BILL.

Original document – Signatures on file with the Clerk of Courts, pursuant to the E-Government Act of 2002.